

SUMMARY

lorazepam

LORAZEPAM XILMAC
4 mg/mL,
solution for injection
Initial inclusion

Original French opinion adopted by the Transparency Committee on
19 July 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions**Clinical Benefit****Premedication before surgery or diagnostic procedures**

- ➔ The objective of premedication before surgery or diagnostic procedures is to induce sedation in order to reduce anxiety. The prescription of such products must be rationally based on the expected benefits and possible associated risks.
- ➔ This is a preventive medicinal product.
- ➔ The efficacy/adverse effects ratio has not been adequately established in view of the data supplied, which have a low level of evidence.
- ➔ In view of the data supplied, which have a low level of evidence, in a context of a marked reduction in the use of premedication in routine practice, associated with a change in clinical practices and the absence of guidelines, particularly concerning premedication by injection, LORAZEPAM XILMAC (lorazepam) 4 mg/mL solution for injection has no role in the care pathway in premedication before surgery or diagnostic procedures in adults and adolescents aged 12 years and above.

➔ Public health benefit

Considering:

- the seriousness of the condition and its prevalence,
- the partially met medical need,
- the lack of additional response to the identified need due to:

- the lack of any demonstrated additional impact on morbidity,
- the lack of a demonstrated additional impact on quality of life,
- the lack of a demonstrated additional impact on the organisation of care in the absence of data,
- and the risk of the onset of harmful consequences of this medicinal product in view of those observed for the class of benzodiazepines and related substances, with an impact on the community,

LORAZEPAM XILMAC (lorazepam) 4 mg/mL solution for injection is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of LORAZEPAM XILMAC (lorazepam) 4 mg/mL solution for injection is insufficient to justify public funding cover in premedication before surgery or diagnostic procedures in adults and adolescents aged 12 years and above.

The Committee issues an unfavourable opinion for inclusion of LORAZEPAM XILMAC (lorazepam) 4 mg/mL solution for injection in the hospital formulary list of reimbursed proprietary medicinal products approved for use in premedication before surgery or diagnostic procedures in adults and adolescents aged 12 years and above and at the MA dosages.

Symptomatic treatment of acute anxiety and agitation in patients unable to take medicines orally

- ➔ Anxiety disorders can progress towards disability and/or a marked deterioration in quality of life. Agitation and aggression during acute and chronic psychotic conditions can pose a danger to patients and their environment.
- ➔ This is a symptomatic medicinal product for emergency use.
- ➔ The efficacy/adverse effects ratio is high.
- ➔ LORAZEPAM XILMAC (lorazepam) 4 mg/mL solution for injection is a therapeutic option in the symptomatic treatment of acute anxiety and agitation in adults and adolescents aged 12 years and above who cannot take medicines orally, for whatever reason.

➔ Public health benefit

Considering:

- the seriousness of the condition and its prevalence,
- the partially met medical need,
- the lack of additional response to the identified need due to:
 - the lack of any demonstrated additional impact on morbidity,
 - the lack of a demonstrated additional impact on quality of life,
- the lack of a demonstrated additional impact on the organisation of care in the absence of data,

LORAZEPAM XILMAC (lorazepam) 4 mg/mL solution for injection is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of LORAZEPAM XILMAC (lorazepam) 4 mg/mL solution for injection is substantial in the treatment of acute anxiety and agitation in adults and adolescents aged 12 years and above who cannot take medicines orally.

The Committee issues a favourable opinion for inclusion of LORAZEPAM XILMAC (lorazepam) 4 mg/mL solution for injection in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the treatment of acute anxiety and agitation in adults and adolescents aged 12 years and above who cannot take medicines orally and at the MA dosages.

Clinical Added Value

Premedication before surgery or diagnostic procedures

Not applicable.

Symptomatic treatment of acute anxiety and agitation in patients unable to take medicines orally

Considering:

- data with a low level of evidence from the literature having assessed the efficacy of lorazepam in this indication,
- the lack of robust comparative data versus the other available alternatives,
- the well-established use of benzodiazepines by injection in this indication,

the Committee considers that LORAZEPAM XILMAC (lorazepam) 4 mg/mL solution for injection provides no clinical added value (CAV V) in the care pathway for the treatment of acute anxiety and agitation in adults and adolescents aged 12 years and above who cannot take medicines orally.